

certify compliance with any applicable Federal, State, and local emissions requirements. List to the extent possible the potentially toxic substances expected to enter the environment at the site(s) of destruction and/or disposal of the article. Describe the approximate concentrations of emissions; state the controls exercised; and include a citation of, and statement of compliance with, applicable requirements at the Federal, State, and local level.

4. *Fate of potentially toxic emitted substances in the environment:* Report physical/chemical and other data in the scientific literature relating to the fate of potentially toxic substances expected to be emitted into the environment as a result of destruction or other disposal of the article. Such physical/chemical parameters include water solubility, solubility in organic solvents, *n*-octanol/water partition coefficient, dissociation constants, vapor pressure, ultraviolet-visible absorption spectrum, ability to form chemical complexes, storage stability, etc.

5. *Environmental effects of potentially toxic substances expected to be emitted into the environment.* Report information on the effects of the emitted substances on animals, plants, humans, other organisms, and effects at the ecosystem level. Compare the expected environmental concentrations of the substances with the concentrations that cause adverse effects.

6. *Description of alternative methods of destruction and/or disposal and the expected environmental consequences:* Describe the environmental impact of reasonable alternatives (including no action) particularly those that will enhance the quality of the environment and that will avoid some or all of the adverse environmental effects of the proposed method of destruction or other disposition.

7. *Comparative analysis of proposed methods of destruction or other disposition and alternative methods:* Provide a comparative analysis of the environmental benefits and risks of the proposed and alternative methods. Identify the preferred action based on environmental factors.

8. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall also be listed.

9. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

(Approved by the Office of Management and Budget under control number 0910-0190)

[50 FR 16656, Apr. 26, 1985, as amended at 50 FR 30267, July 25, 1985]

#### **§25.32 Finding of no significant impact.**

(a) As defined by the CEQ regulations (40 CFR 1508.13), a finding of no significant impact (FONSI) is a document prepared by a Federal agency and stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) If the EA has been prepared by an applicant or petitioner, the agency may choose to include additional evidence in the FONSI. Any remaining unknowns or uncertainties will be identified.

(c) The agency official(s) responsible for the preparation and approval of the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusions not to prepare an EIS for the action under consideration.

#### **§25.33 Notice of intent.**

(a) As defined by CEQ regulations (40 CFR 1508.22), the Notice of Intent notifies the public that the agency has determined that an EIS will be prepared. This determination may be based on information contained in an EA or on other information available to the agency which indicates that potentially significant effects may be associated with a proposed action.

(b) As required by 40 CFR 1508.22, the Notice of Intent will describe the proposed action, possible alternatives, the agency's proposed scoping process, which may include a request for information or suggestions regarding the scope of the EIS and notice of public meetings, and the identification of persons within the agency to contact for further information.

#### **§25.34 Draft, final, and supplemental environmental impact statements.**

(a) The CEQ regulations (40 CFR part 1502) provide detailed requirements for the preparation of an EIS. CEQ's format for EIS's (40 CFR 1502.10) will be followed unless the agency determines that there is a compelling reason to do otherwise.

(b) When chemical substances enter the environment as a result of a proposed action or other regulatory alternatives, the portion of the EIS format on *environmental consequences* (40 CFR 1502.10(g)) will include discussion of the environmental fates and effects of those substances similar to that described in § 25.31a.

(c) Any final EIS will contain any additional information gathered by the agency after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and the agency's responses to the comments as required in 40 CFR 1503, including any revisions resulting from comments or other information.

(d) Draft and final supplemental EIS's will conform to the EIS format (40 CFR 1502.10) unless there is a compelling reason to do otherwise.

#### Subpart D—Agency Decisionmaking

##### **§ 25.40 Procedures for incorporating environmental considerations into agency decisionmaking.**

(a) These procedures are to ensure that environmental information is provided to decisionmakers in a timely manner. The NEPA process is an integral part of FDA's decisionmaking. Agency decisionmakers ensure that the policies and purpose of NEPA and CEQ regulations are complied with by:

(1) Completing or assuring the completion of an EA, determining whether an EIS is required and, ordinarily, completing a draft EIS (if one is required) prior to or at the time of proposing an action subject to §§ 25.21 and 25.22.

(2) Including in decision documents and supporting environmental documents a discussion of all alternatives considered in the decision as required by 40 CFR 1502.14. Every action memorandum proposing an agency action included under § 25.21 or § 25.22 will contain an evaluation of the environmental impact of the proposed action and will be accompanied by a draft or final EIS if one is required.

(3) Submitting relevant environmental documents, comments, and responses with other decision documents through the review process.

(4) Including in the records of proceedings any appropriate environmental documents, comments, and responses.

(5) Completing and circulating a final EIS before the decision to implement an action that significantly affects the quality of the human environment.

(b) There are certain regulatory actions which, because of their immediate importance to the public health, make adherence to the requirements of the CEQ regulations and these regulations concerning minimum periods of public review impractical. Compliance with the requirements for environmental analysis under NEPA is impossible where emergency circumstances require immediate regulatory action to safeguard the public health. For such actions, the responsible agency official shall consult with the CEQ about alternative arrangements before the action is taken, or after the action is taken, if time does not permit prior consultation with CEQ.

(c) Certain FDA actions are subject to statutory time limits that sometimes do not provide sufficient time to complete the required environmental document. Should the responsible agency official be unable to complete environmental consideration of the proposed action before a notice of filing of a food or color additive petition is required to be published, and if the subsequent environmental analysis leads to the conclusion that no EIS is necessary, the FEDERAL REGISTER document publishing the final regulation rather than the notice of filing shall state that no EIS is necessary and that the FONSI and the EA are available upon request and filed in the FDA Dockets Management Branch. If it is concluded that an EIS is necessary, the final regulation, final EIS, and record of decision shall be made available as prescribed in 40 CFR 1506.10.

##### **§ 25.41 Actions for which a finding of no significant impact and an environmental assessment are prepared.**

(a) As required by 40 CFR 1501.4(e), a FONSI is prepared for an individual action or groups of related actions that will not significantly affect the quality